



From-elan drug delivery



+6103138845

T-133 P.007/015 F-346

UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER
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18

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

This Office Action is in response to Paper # 17, filed July 8, 2002, and the sequence listing filed June 28, 2002.

The communication filed June 28, 2002 is not fully responsive to the Office communication mailed January 2, 2002 for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules or Raw Sequence Listing Error Report. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Since the above-mentioned reply appears to be bona fide attempt to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), applicant is given a TIME PERIOD of ONE (1) MONTH from the mailing date of this communication within which to correct the deficiency so as to comply with the sequence rules (37 CFR 1.821 - 1.825) in order to avoid abandonment of the application under 37 CFR 1.821(g). EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

APPLICANTS SHOULD SEND THE DISK TO THE ARLINGTON ADDRESS HIGHLIGHTED ON THE CFR PROBLEM REPORT. APPLICANTS APPEAR TO BE SENDING THE DISK TO THE DC ADDRESS, WHEREIN THE DISK PASSES THROUGH THE POST OFFICE'S BRENTWOOD FACILITY WHERE IT IS IRRADIATED FOR ANTHRAX AND THEREBY DAMAGED.

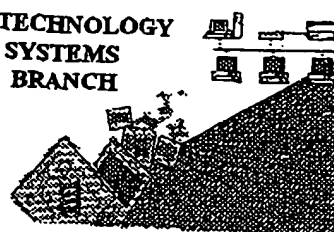
Also noted is that Applicants have submitted amendments wherein the amino acid sequence is provided using the single letter code rather than the triple letter code as required under 37 CFR 1.821. Correction of these and any other single letter reference to amino acids is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D., whose telephone number is (703) 308-0034. The examiner can normally be reached Monday-Friday from 6:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph.D., can be reached on (703) 308-2923. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Karen Cochrane Carlson (Ph.D.)*  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER

BIOTECHNOLOGY  
SYSTEMS  
BRANCH

p#15

**RAW SEQUENCE LISTING  
ERROR REPORT**

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/443,986B  
 Source: Lee Rush  
 Date Processed by STIC: 7/2/2002

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.

PATENTIN 2.1 e-mail help: [patin21help@uspto.gov](mailto:patin21help@uspto.gov) or phone 703-306-4119 (R. Wax)

PATENTIN 3.0 e-mail help: [patin3help@uspto.gov](mailto:patin3help@uspto.gov) or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER  
VERSION 3.1 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND  
TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom. Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/efb/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
3. Hand Carry directly to:  
 U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7<sup>th</sup> Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202  
 Or  
 U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
4. Federal Express, United Parcel Service, or other delivery service to: U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

Revised 01/29/2002

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TECH CENTER 1600/2900



1600

## RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/443,986B

DATE: 07/02/2002

TIME: 10:17:32

Input Set : A:\EP.txt

Output Set: N:\CRF3\07022002\I443986B.raw

Does Not Comply

Corrected Diskette Needed

3 <110> APPLICANT: Elan Corporation  
4 O'Mahony, Daniel J.  
6 <120> TITLE OF INVENTION: RETRO-INVERSION PEPTIDES THAT TARGET GIT TRANSPORT RECEPTORS  
ND RELATED  
7 METHODS  
9 <130> FILE REFERENCE: 99.1064.US/E1067/20019  
11 <140> CURRENT APPLICATION NUMBER: US 09/443,986B  
12 <141> CURRENT FILING DATE: 1999-11-19  
14 <160> NUMBER OF SEQ ID NOS: 85  
16 <170> SOFTWARE: PatentIn version 3.1  
18 <210> SEQ ID NO: 1  
19 <211> LENGTH: 15  
20 <212> TYPE: PRT  
21 <213> ORGANISM: Artificial  
23 <220> FEATURE:  
24 <223> OTHER INFORMATION: PAX2 15 mer fragment-D form retroinversion  
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29 1 5 10 15  
32 <210> SEQ ID NO: 2  
33 <211> LENGTH: 16  
34 <212> TYPE: PRT  
35 <213> ORGANISM: Artificial  
37 <220> FEATURE:  
38 <223> OTHER INFORMATION: P31 16 mer fragment- D form retroinversion  
40 <400> SEQUENCE: 2  
42 Gly Pro His Arg Arg Gly Arg Pro Asn Ser Arg Ser Ser Lys Arg Thr  
43 1 5 10 15  
46 <210> SEQ ID NO: 3  
47 <211> LENGTH: 14  
48 <212> TYPE: PRT  
49 <213> ORGANISM: Artificial  
51 <220> FEATURE:  
52 <223> OTHER INFORMATION: HAX42 14 mer fragment-D form retroinversion  
54 <400> SEQUENCE: 3  
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57 1 5 10  
60 <210> SEQ ID NO: 4  
61 <211> LENGTH: 15  
62 <212> TYPE: PRT  
63 <213> ORGANISM: Artificial  
65 <220> FEATURE:  
66 <223> OTHER INFORMATION: PAX2 15 mer fragment  
68 <400> SEQUENCE: 4

## RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/443,986B

DATE: 07/02/2002

TIME: 10:17:32

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Output Set: N:\CRF3\07022002\I443986B.raw

70 Thr Asn Ala Lys His Ser Ser His Asn Arg Arg Leu Arg Thr Arg  
71 1 5 10 15  
74 <210> SEQ ID NO: 5  
75 <211> LENGTH: 16  
76 <212> TYPE: PRT  
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79 <220> FEATURE:  
80 <223> OTHER INFORMATION: P31 16 mer fragment  
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85 1 5 10 15  
88 <210> SEQ ID NO: 6  
89 <211> LENGTH: 14  
90 <212> TYPE: PRT  
OK> 91 <213> ORGANISM: Artificial  
93 <220> FEATURE:  
94 <223> OTHER INFORMATION: HAX42 14 mer fragment  
96 <400> SEQUENCE: 6  
98 Pro Gly Asp Tyr Asn Cys Cys Gly Asn Gly Asn Ser Thr Gly  
99 1 5 10  
102 <210> SEQ ID NO: 7  
103 <211> LENGTH: 40  
104 <212> TYPE: PRT  
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107 <220> FEATURE:  
108 <223> OTHER INFORMATION: PAX2 full length  
110 <400> SEQUENCE: 7  
112 Ser Thr Pro Pro Ser Arg Glu Ala Tyr Ser Arg Pro Tyr Ser Val Asp  
113 1 5 10 15  
116 Ser Asp Ser Asp Thr Asn Ala Lys His Ser Ser His Asn Arg Arg Leu  
117 20 25 30  
120 Arg Thr Arg Ser Arg Pro Asn Gly  
121 35 40  
124 <210> SEQ ID NO: 8  
125 <211> LENGTH: 44  
126 <212> TYPE: PRT  
--> 127 <213> ORGANISM: Artificial  
129 <220> FEATURE:  
130 <223> OTHER INFORMATION: HAX42 full length with additional L-Lysine  
132 <220> FEATURE:  
133 <221> NAME/KEY: MOD\_RES  
134 <222> LOCATION: (1)..(1)  
135 <223> OTHER INFORMATION: Dansylated L-Lysine  
138 <400> SEQUENCE: 8  
140 Ser Asp His Ala Leu Gly Thr Asn Leu Arg Ser Asp Asn Ala Lys Glu  
141 1 5 10 15  
144 Pro Gly Asp Tyr Asn Cys Cys Gly Asn Gly Asn Ser Thr Gly Arg Lys  
145 20 25 30  
148 Val Phe Asn Arg Arg Arg Pro Ser Ala Ile Pro Thr

"Ser" is at location 1

## RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/443,986B

DATE: 07/02/2002

TIME: 10:17:32

Input Set : A:\EP.txt

Output Set: N:\CRF3\07022002\I443986B.raw

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149          35          40
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153 <211> LENGTH: 16
154 <212> TYPE: PRT
155 <213> ORGANISM: Artificial
157 <220> FEATURE:
158 <223> OTHER INFORMATION: ZElan 144; PAX2 15 mer fragment-D form retroinversion with
addi
159          tional L-lysine in position 1
161 <220> FEATURE:
162 <221> NAME/KEY: MOD_RES
163 <222> LOCATION: (1)..(1)
164 <223> OTHER INFORMATION: Dansylated L-lysine
167 <400> SEQUENCE: 9
169 Lys Arg Thr Arg Leu Arg Arg Asn His Ser Ser His Lys Ala Asn Thr
170 1          5          10          15
173 <210> SEQ ID NO: 10
174 <211> LENGTH: 17
175 <212> TYPE: PRT
176 <213> ORGANISM: Artificial
178 <220> FEATURE:
179 <223> OTHER INFORMATION: ZElan 145; P31 16 mer fragment- D form retroinversion with
additi
180          onal L-lysine in position 1
182 <220> FEATURE:
183 <221> NAME/KEY: MOD_RES
184 <222> LOCATION: (1)..(1)
185 <223> OTHER INFORMATION: dansylated L-lysine
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190 Lys Gly Pro His Arg Arg Gly Arg Pro Asn Ser Arg Ser Ser Lys Arg
191 1          5          10          15
194 Thr
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199 <211> LENGTH: 15
200 <212> TYPE: PRT
201 <213> ORGANISM: Artificial
203 <220> FEATURE:
204 <223> OTHER INFORMATION: ZElan 146; HAX42 14 mer fragment-D form retroinversion with
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205          ional L-Lysine in position 1
207 <220> FEATURE:
208 <221> NAME/KEY: MOD_RES
209 <222> LOCATION: (1)..(1)
210 <223> OTHER INFORMATION: dansylated L-Lysine
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215 Lys Gly Thr Ser Asn Gly Asn Gly Cys Cys Asn Tyr Asp Gly Pro
216 1          5          10          15
219 <210> SEQ ID NO: 12
220 <211> LENGTH: 16
221 <212> TYPE: PRT
222 <213> ORGANISM: Artificial
224 <220> FEATURE:

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## RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/443,986B

DATE: 07/02/2002

TIME: 10:17:32

Input Set : A:\EP.txt

Output Set: N:\CRF3\07022002\I443986B.raw

225 <223> OTHER INFORMATION: ZElan 129; PAX2 15 mer fragment with additional L-Lysine in  
posi  
226 tion 1  
228 <220> FEATURE:  
229 <221> NAME/KEY: MOD\_RES  
230 <222> LOCATION: (1)..(1)  
231 <223> OTHER INFORMATION: dansylated L-Lysine  
234 <400> SEQUENCE: 12  
236 Lys Thr Asn Ala Lys His Ser Ser His Asn Arg Arg Leu Arg Thr Arg  
237 1 5 10 15  
240 <210> SEQ ID NO: 13  
241 <211> LENGTH: 17  
242 <212> TYPE: PRT  
Q- 243 <213> ORGANISM: Artificial  
245 <220> FEATURE:  
246 <223> OTHER INFORMATION: ZElan 031; P31 16 mer fragment with additional L-Lysine in  
positi  
247 on 1  
249 <220> FEATURE:  
250 <221> NAME/KEY: MOD\_RES  
251 <222> LOCATION: (1)..(1)  
252 <223> OTHER INFORMATION: dansylated L-Lysine  
255 <400> SEQUENCE: 13  
257 Lys Thr Arg Lys Ser Ser Arg Ser Asn Pro Arg Gly Arg Arg His Pro  
258 1 5 10 15  
261 Gly  
265 <210> SEQ ID NO: 14  
266 <211> LENGTH: 15  
Q- 267 <212> TYPE: PRT  
268 <213> ORGANISM: Artificial  
270 <220> FEATURE:  
271 <223> OTHER INFORMATION: ZElan 091; HAX42 14 mer fragment with additional L-lysine in  
posi  
272 tion 1  
274 <220> FEATURE:  
275 <221> NAME/KEY: MOD\_RES  
276 <222> LOCATION: (1)..(1)  
277 <223> OTHER INFORMATION: dansylated L-lysine  
280 <400> SEQUENCE: 14  
282 Lys Pro Gly Asp Tyr Asn Cys Cys Gly Asn Gly Asn Ser Thr Gly  
283 1 5 10 15  
286 <210> SEQ ID NO: 15  
287 <211> LENGTH: 40  
288 <212> TYPE: PRT  
Q- 289 <213> ORGANISM: Artificial  
291 <220> FEATURE:  
292 <223> OTHER INFORMATION: PAX2 full length with additional L-lysine in position 1  
294 <220> FEATURE:  
295 <221> NAME/KEY: MOD\_RES  
296 <222> LOCATION: (1)..(1)  
297 <223> OTHER INFORMATION: dansylated L-Lysine  
300 <400> SEQUENCE: 15

Ser is at location 1

see p.5

## RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/443,986B

DATE: 07/02/2002

TIME: 10:17:32

Input Set : A:\EP.txt

Output Set: N:\CRF3\07022002\I443986B.raw

302 Ser Thr Pro Pro Ser Arg Glu Ala Tyr Ser Arg Pro Tyr Ser Val Asp  
303 1 5 10 15  
306 Ser Asp Ser Asp Thr Asn Ala Lys His Ser Ser His Asn Arg Arg Leu  
307 20 25 30  
310 Arg Thr Arg Ser Arg Pro Asn Gly  
311 35 40

314 &lt;210&gt; SEQ ID NO: 16

315 &lt;211&gt; LENGTH: 44

316 &lt;212&gt; TYPE: PRT

317 &lt;213&gt; ORGANISM: Artificial

319 &lt;220&gt; FEATURE:

320 &lt;223&gt; OTHER INFORMATION: S15 44 mer fragment L-form

322 &lt;400&gt; SEQUENCE: 16

324 Arg Ser Gly Ala Tyr Glu Ser Pro Asp Gly Arg Gly Gly Arg Ser Tyr  
325 1 5 10 15

328 Val Gly Gly Gly Gly Gly Cys Gly Asn Ile Gly Arg Lys His Asn Leu  
329 20 25 30

332 Trp Gly Leu Arg Thr Ala Ser Pro Ala Cys Trp Asp  
333 35 40

336 &lt;210&gt; SEQ ID NO: 17

337 &lt;211&gt; LENGTH: 44

338 &lt;212&gt; TYPE: PRT

339 &lt;213&gt; ORGANISM: Artificial

341 &lt;220&gt; FEATURE:

342 &lt;223&gt; OTHER INFORMATION: S21 44 mer fragment L-form

344 &lt;400&gt; SEQUENCE: 17

346 Ser Pro Arg Ser Phe Trp Pro Val Val Ser Arg His Glu Ser Phe Gly  
347 1 5 10 15

350 Ile Ser Asn Tyr Leu Gly Cys Gly Tyr Arg Thr Cys Ile Ser Gly Thr  
351 20 25 30

354 Met Thr Lys Ser Ser Pro Ile Tyr Pro Arg His Ser  
355 35 40

358 &lt;210&gt; SEQ ID NO: 18

359 &lt;211&gt; LENGTH: 44

360 &lt;212&gt; TYPE: PRT

361 &lt;213&gt; ORGANISM: Artificial

363 &lt;220&gt; FEATURE:

364 &lt;223&gt; OTHER INFORMATION: S22 44 mer fragment L-form

366 &lt;400&gt; SEQUENCE: 18

368 Ser Ser Ser Ser Asp Trp Gly Gly Val Pro Gly Lys Val Val Arg Glu  
369 1 5 10 15

372 Arg Phe Lys Gly Arg Gly Cys Gly Ile Ser Ile Thr Ser Val Leu Thr  
373 20 25 30

376 Gly Lys Pro Asn Pro Cys Pro Glu Pro Lys Ala Ala  
377 35 40

380 &lt;210&gt; SEQ ID NO: 19

381 &lt;211&gt; LENGTH: 44

382 &lt;212&gt; TYPE: PRT

383 &lt;213&gt; ORGANISM: Artificial

RAW SEQUENCE LISTING ERROR SUMMARY  
PATENT APPLICATION: US/09/443,986B

DATE: 07/02/2002  
TIME: 10:17:33

Input Set : A:\EP.txt

Output Set: N:\CRF3\07022002\I443986B.raw

Please Note:

Use of n and/or Xaa have been detected in the Sequence Listing. Please review the Sequence Listing to ensure that a corresponding explanation is presented in the <220> to <223> fields of each sequence which presents at least one n or Xaa.

Seq#:73; Xaa Pos. 1,3,4,6,7,8,10

Seq#:74; Xaa Pos. 2,4,7,8

Seq#:75; Xaa Pos. 7,8

Invalid Line Length:

The rules require that a line not exceed 72 characters in length. This includes spaces.

Seq#:1; Line(s) 6

Invalid <213> Response:

Use of "Artificial" only as "<213> Organism" response is incomplete, per 1.823(b) of New Sequence Rules. Valid response is Artificial Sequence.

Seq#:1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27

Seq#:28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51

Seq#:52,53,54,55,56,57,58,59,60,61,62,63,64,65,66,67,68,69,70,71,72,73,74,75

Seq#:76,77,78,79,80,81,82,83,84,85



Application No.: 09/ 443986

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: the specification and the claims do not have sequence identification numbers at each sequence as required by 37 CFR 1.821(d).

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

For PatentIn software help, call (703) 308-6856

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**